EXHIBIT 102

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

- - -

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	:	HON. DAN A. POLSTER
APPLIES TO ALL CASES	:	NO. 1:17-MD-2804

- HIGHLY CONFIDENTIAL -
SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

- - -

JANUARY 22, 2019

- - -

Videotaped sworn deposition of BRIAN LORTIE, taken pursuant to notice, was held at McCARTER & ENGLISH, LLP, 1600 Market Street, Suite 3900, Philadelphia, Pennsylvania, beginning at 9:06 a.m., on the above date, before Margaret M. Reihl, a Registered Professional Reporter, Certified Shorthand Reporter, Certified Realtime Reporter, and Notary Public.

- - -

GOLKOW LITIGATION SERVICES
877.370.3377 ph | 917.591.5672 fax
deps@golkow.com

Page 526

it is, yes.
Q. Okay. And then going to the first page of the exhibit, which is Bates stamped 01563548?
A. Before I do, I think you read -- I just want too make sure we're correct, so you talked about the bill -- or sorry -- the subject of the e-mail from Burt Rosen to the long number of addressees, and then it says "Please see this request from Wade at the American Society for Pain Management Nursing. Wade is requesting a timely reply from your organization." Is that the -- that's what you wanted me to see, right?
Q. Right. I want to see that that's identifying -- you asked who Mr. Delk was, and it's identifying him as being from the American Society For Pain Management Nursing.
A. Thank you. Yep.
Q. Do you see that?
A. Yes.
Q. And then on the very first page of the exhibit, you see that -- so Mr. Munroe has forwarded this communication to you, among others, at Endo, correct?

Page 527

A. Munroe to me and others, yes.
Q. And your response at the very top of the page, Exhibit 47, was what?
A. I sent a note to Brian, Deb Logan, Neil Shusterman, Matt Maletta, Jen Dubas, John Harlow, Timothy Byrne, Keri Mattox and Andrew Scott, and I wrote "well done."
Q. So you're congratulating Mr. Munroe on this coordinated effort through the Pain Care Forum members to communicate their opposition to implementation of the CDC guidelines as set forth in the draft communication we looked at, the last two pages of the exhibit?
MR. LIMBACHER: Object to form.
THE WITNESS: Is that a question?
BY MS. SCULLION:
Q. Is that what you were congratulating him on?
A. No, I don't believe that's the case. I can't draw that conclusion from reading what you've presented to me.
MS. SCULLION: Okay. We can take a break.

Page 528

MR. LIMBACHER: Thank you.
THE VIDEOGRAPHER: Off the record, 4:16.
(Brief recess.)
THE VIDEOGRAPHER: We are back on the record at 4:33.
BY MS. SCULLION:
Q. Mr. Lortie, asking you in your capacity as a corporate representative, with respect to the effectiveness of Endo's anti-diversion procedures, did Endo ever determine that any prescriptions of Opana ER were medically unnecessary?
A. Is your question did Endo ever determine that any individual prescription was medically unnecessary?
Q. We can start with that.
A. I'm not aware of whether the company did or did not. That's a level of detail I'm not familiar with.
Q. Same question, though, but with respect to did Endo -- strike that.
Did Endo ever determine that any prescriptions of Opana ER were medically

Page 529

unnecessary at some higher level, not just individually, but at a higher level?
MR. LIMBACHER: Object to form.
THE WITNESS: Yes, I'm sure that there were cases that would fall under that heading, yes.
BY MS. SCULLION:
Q. Does Endo have records indicating findings that certain cases I think as you said were determined to be medically unnecessary?
MR. LIMBACHER: Object to form.
THE WITNESS: I don't know specifically, but I would -- I would think that our pharmacovigilance and drug safety department would have maintained such records.
BY MS. SCULLION:
Q. Did you review any such records in preparation for today's deposition?
A. No, not specifically at that level of detail, no.
Q. Okay. As part of Endo's anti-diversion efforts, did Endo monitor for signals that Opana ER had street value?

Page 530

MR. LIMBACHER: Object to form.
THE WITNESS: I believe that whether it was actively -- as a result of active monitoring or as a result of -- well, let me restate that.
As part of the internet surveillance and other surveillance of media and chat rooms and the like that are part of the RiskMAP and subsequently added to by the REMS, that that was part of what the team did, and then those things were reviewed at the -- my understanding is reviewed at the Risk Management Committee level.
BY MS. SCULLION:
Q. And in terms of the effectiveness of Endo's procedures you just described, did Endo, in fact, see evidence that Opana ER had a street value?
MR. LIMBACHER: Object to form and to the extent it falls outside the scope of the topics he's been designated.
THE WITNESS: Yeah, my answer was

Page 531

regarding the question of did Endo monitor for that.
BY MS. SCULLION:
Q. Yes.
A. And the answer was yes. Beyond that, I don't know.
Q. That's what I'm asking. In terms of understanding the effectiveness of its monitoring, do you know whether those -- that monitoring was, in fact, effective to pick up signals that Opana ER had street value?
MR. LIMBACHER: Same objections.
THE WITNESS: I don't know. I mean, the monitoring was done. I'm not sure how you quantify effectiveness of monitoring. By virtue of monitoring, you see things that are posted, and that's reviewed by the Risk Management Committee, but I don't know beyond that how to quantify the effectiveness in that context.
BY MS. SCULLION:
Q. Do you understand, though, that Endo did, in fact, see evidence that Opana ER

Page 532

early on had street value?
MR. LIMBACHER: Object to form.
THE WITNESS: I don't recall that specifically. I didn't sit on that committee, so I, you know, wasn't familiar with that.
MS. SCULLION: Can I have E1585, please.
(Document marked for identification as Endo-Lortie Deposition Exhibit No. 48.)
BY MS. SCULLION:
Q. I'm going to hand you what's been marked as Exhibit Number 48.
And Exhibit 48 is Bates stamped ENDO-OPIOID_MDL-00774063, and we've marked it E1585 in the top right-hand corner.
Mr. Munroe, I'd like to direct your attention to page E1585.3.
A. I think you mean Mr. Lortie but --
Q. I am so sorry.
A. He's the other Brian.
Q. Thank you, Mr. Lortie. I direct

Page 533

your attention to page E1585.3. You see at the bottom, there's an e-mail from John Bullock to Sherri Ferstler. And the content of that e-mail starts at the bottom of 1585.3 and continues all the way through 1585.5. I just want to orient you to the document.
MR. LIMBACHER: Are we asking him now in his capacity as a fact witness?
MS. SCULLION: Sure.
THE WITNESS: Okay. So I see that e-mail that starts on the bottom of 1585.3. Would you like me to read that?
BY MS. SCULLION:
Q. Sure. You can go ahead and read through that.
A. Okay. Thank you. Give me a moment to do that.
(Witness reviews document.)
Okay. I've read that e-mail. Thank you.
Q. Okay. And do you see the e-mail is forwarding on an article from the Paducah Sun dated December 10th, 2007 concerning an overdose death being investigated by the Marshall sheriff's office?

Page 534

A. Yes, December 10th is on the next page.
Q. Right.
A. It evidently refers to it in the e-mail as December 11th, but, yes, it appears to be following -- sorry -- forwarding along that newspaper article.
Q. And if you go down on page 1585.4 within the body of the article, go towards the last quarter of that page where it begins the words Miranda Minter-Banister.
Do you see that?
A. Yes, I do.
Q. Do you see this is conveying that Miranda Minter-Banister, age 27, of Benton, Kentucky died at her home and it was after using an Opana pill purchased, says Minter-Banister bought a second Opana pill for $30 from Spiceland that Minter-Banister and her husband later inhaled.
Do you see that?
MR. LIMBACHER: Object to form.
THE WITNESS: I mean, you've picked a couple of lines out of that --

Page 535

out of that paragraph, but I see where you're reading that, yes.
BY MS. SCULLION:
Q. So this is referring to a purchase of Opana other than through a prescription, correct?
A. It could be. I mean, I'm reading it at the same time you are.
Q. Right. It's referring to someone buying an Opana pill from another person, a neighbor or a friend, correct?
MR. LIMBACHER: Object to form.
THE WITNESS: It appears that that could be the case.
BY MS. SCULLION:
Q. Okay. And then if you go right above that paragraph, you see the paragraph that says Opana is similar to the painkiller OxyContin and it goes by the street name.
And what's the street name indicated here for Opana?
A. You're asking me that?
Q. Yeah.
A. You'd like me to read that?

Page 536

Q. Yeah.
A. It has the words stop sign in quotation marks.
Q. Right. So by this time Opana -- at least by this time, Opana is not only being sold but, in fact, has a street name; that's what the article is conveying, right?
MR. LIMBACHER: Object to form.
THE WITNESS: It is -- it is suggesting that for some reason the author is reporting that it goes by the street name stop sign. That's what it says.
BY MS. SCULLION:
Q. And you saw other similar media reports during your time at Endo, correct, conveying that Opana ER was being bought and sold on the street, had street value, had a street name, was resulting in overdose deaths, correct?
MR. LIMBACHER: Object to form and foundation.
THE WITNESS: I don't recall that. That was certainly not a regular

Page 537

part of my responsibilities.
BY MS. SCULLION:
Q. You don't recall ever seeing any media reports about Opana ER contributing to the opioid epidemic?
A. From time to time I'm sure things were forwarded along, as this one appears to have been. This one actually predates me by some time, but I don't recall any specific ones, and it was not a routine part of my job responsibilities to review media reports.
Q. And you recall, though, that you were employed by Endo in 2011, correct?
A. Yes.
Q. And where was your office?
A. In 2011 where was my office? It was in --
Q. What town?
A. Chaddsford.
Q. Pennsylvania?
A. Yes.
Q. That's just outside of Philadelphia?
A. It's 15 or 20 miles outside of

Page 538

Philadelphia.
Q. And do you recall in 2011 that the Philadelphia office of the DEA specifically issued an alert with respect to Opana's -- Opana ER's street use and its contribution to the opioid epidemic?
MR. LIMBACHER: Object to form.
THE WITNESS: Do I recall that?
BY MS. SCULLION:
Q. Yes.
A. I do not recall that.
MS. SCULLION: Can I have E563, please.
(Document marked for identification as Endo-Lortie Deposition Exhibit No. 49.)
BY MS. SCULLION:
Q. I hand you what's been marked as Exhibit Number 49.
And Exhibit 49 is Bates stamped ENDO-OR-CID-00694084. And, Mr. Lortie, it bears number E563 at the top right-hand corner, correct?
A. Yes, I have that document.

Page 539

Q. Okay. In 2011 did you have any responsibilities as part of your product portfolio for Opana ER?
A. I had commercial responsibilities, yes, I think we've already established that.
Q. If you go to page E563.2, do you see this is a Drug Intelligence Brief from the Philadelphia Division Intelligence Program for Drug Enforcement Administration?
A. That's how it's titled, yes. I see that on the top of the document.
Q. And what is the title of this Drug Intelligence Brief itself?
A. Underneath the header that says "Drug Intelligence Brief," it says "Opana (Oxymorphone) Abuse."
Q. And can you read the summary of this Drug Intelligence Brief, please.
A. You'd like me to read what the summary statement is?
Q. Yeah, what the DEA has stated in its summary here?
A. So underneath the headline it

Page 540

says, "Summary, the Philadelphia Division Intelligence Program received information on a possible emerging trend in the region; Oxymorphone (brand name Opana) has been reported by several sources of information as the 'big thing right now' in pharmaceutical drug abuse in the region."
Q. And Endo was aware in at least May 2011 that, in fact, Opana ER was being reported as the big thing right now in pharmaceutical drug abuse, at least in the Philadelphia region; is that correct?
MR. LIMBACHER: Object to form and foundation.
THE WITNESS: So I have not seen this before. At least I don't recall seeing it before, so I can't attest to whether or not the company saw this.
I can say that I don't recognize seeing it.
BY MS. SCULLION:
Q. You don't recall ever, as someone with commercial responsibility for Opana ER in May of 2011, ever being told that the

Page 541

Philadelphia Division Intelligence Program, the DEA was issuing a brief indicating that the product you had commercial responsibility for was the big thing right now in pharmaceutical drug abuse in the region?
MR. LIMBACHER: Object to form.
BY MS. SCULLION:
Q. It never came to your attention?
A. I don't recall seeing this, no.
Q. Okay. And among other things, this Drug Intelligence Brief confirms, if you look in the details section below the summary --
A. Still on the same page, .2?
Q. Correct.
You see the details section confirms that not only is Opana being reported as of May 2011 as the big thing right now in pharmaceutical drug abuse, but that "in the early 1970s, oxymorphone in the form of Numorphan instant-release tablets was one of the most sought-after and well-regarded opioids of the class IV community."
Do you see that?
A. Yes, I see the sentence that you

Page 542

just read.
Q. And then it goes -- and it goes on to explain that oxymorphone in the form of Numorphan instant-release tablets, in fact, had a street name popularly known as "blues" for their blue coloring.
Do you see that?
MR. LIMBACHER: Object to form.
THE WITNESS: I see the line you just read, it's a part of the next sentence.
BY MS. SCULLION:
Q. Okay. So, again, so the DEA is not only confirming that as of May 2011 Opana ER is being abused as a street drug, but, in fact, oxymorphone had a history of such abuse, correct?
MR. LIMBACHER: Object to form.
THE WITNESS: You read the summary, you read the details, so I think the text explains apparently what the DEA was reporting.
BY MS. SCULLION:
Q. And you don't have any reason to

Page 543

dispute what the DEA, the federal agency charged with enforcement of laws concerning Opana ER and other narcotics, you don't dispute their assessment of Opana ER's street use, do you?
MR. LIMBACHER: Object to form.
THE WITNESS: Providing this is truly a DEA brief, no, I don't have any grounds to dispute DEA actions.
BY MS. SCULLION:
Q. Okay.
MR. LIMBACHER: Counsel, Exhibit 49 has on the first page "Attachment 16." Was this part of a larger document?
MS. SCULLION: I will tell you it was produced to us this way, so I do not know.
MR. LIMBACHER: Would it be with other attachments?
MS. SCULLION: I do not know, sitting here.
MR. LIMBACHER: So you don't know to what it was attached to --
MS. SCULLION: Or not attached.

Page 544

MR. LIMBACHER: -- or what it was part of?
MS. SCULLION: I do not.
BY MS. SCULLION:
Q. You said that in connection with your preparation for the deposition, you did review some of the RiskMAP updates that Endo submitted for Opana ER to the FDA, right?
A. Yes.
Q. And do you recall that those RiskMAP updates did include discussions of cases of apparent abuse of Opana ER from time to time?
A. Generally, from time to time, yes. Again, I didn't review every single one, but just to refresh my recollection or to understand that these were regular part of the risk management team's activities.
Q. And those reports also showed from time to time overdoses from Opana ER, correct?
MR. LIMBACHER: Object to form.
THE WITNESS: I would put those under the same heading as adverse events.

Page 545

BY MS. SCULLION:
Q. So deaths from Opana ER?
MR. LIMBACHER: Object to form.
THE WITNESS: I do think that the one I reviewed that I did see that, but, again, I don't recall the details. I wasn't reviewing it at that level of detail.
BY MS. SCULLION:
Q. And showed reference to street use of Opana ER, correct?
MR. LIMBACHER: Object to form.
THE WITNESS: If there's a specific report that you'd like me to look at, I could probably give you more information.
BY MS. SCULLION:
Q. Do you recall those same indications that Opana ER was being abused, including by people buying and selling Opana ER?
MR. LIMBACHER: Object to form.
THE WITNESS: I know in the records that I reviewed, I don't specifically recall that, but, again, as

Page 546

I said, I'd be happy to review a specific one, if you'd like, if that would be helpful.
MS. SCULLION: Let's see if we can. Can we have the Q1 2008 RiskMAP update.
(Document marked for identification as Endo-Lortie Deposition Exhibit No. 50.)
BY MS. SCULLION:
Q. Let me hand you what's been marked as Exhibit 50.
And Exhibit 50 is Bates stamped ENDO-CHI_LIT-00032209. And, Mr. Lortie, this does not bear an E number.
A. Okay, thank you.
Q. This is the RiskMAP update report for Opana ER dated May 22nd, 2008 covering the period January 1st, 2008 to March 31, 2008, correct?
A. Yes, that's the date that's on the title page.
Q. And if you'll turn to page 20 of the update report, the page numbers are in the

Page 547

upper right-hand corner.
A. Yes, got it.
Q. And if you'll go to the section "6. Post Marketing Surveillance," section "6.1 Periodic Reports," going down to the subheading "Drug Abuse/Intentional Drug misuse."
Are you with me?
A. Yeah, I'm just going to kind of orient myself here.
Q. Yep.
A. (Witness reviews document.)
Okay. And you'd like me to look at the subsection?
Q. The subsection "Drug Abuse/Intentional Drug Misuse."
A. Okay.
Q. Are you there?
A. Yes, I'm focused on that.
Q. Okay. And in this update report, Endo has reported to the FDA "There were 7 reports related to drug abuse and misuse of Opana ER," correct?
A. That's what the sentence says, yes.

Page 548

Q. That's what Endo told the FDA in this report, correct?
MR. LIMBACHER: Object to form.
THE WITNESS: Yes, that's what's written in the report.
BY MS. SCULLION:
Q. And then Endo further told the FDA, "In all 7 reports, Opana ER was misused by crushing and snorting the tablets," correct?
A. Yes, that's what it says.
Q. And then if you'll go down to the sentence that begins, "another report."
A. Yes.
Q. You see that?
A. On the fourth line.
Q. And this is indicating -- sorry, strike that.
In this sentence Endo has told the FDA that "Another report (OPER20080023) involved a 45-year-old man who was a known drug abuser being treated for drug addiction, was purchasing Opana ER 40 mg tablets with a twenty-dollar co-pay and was also buying the product on the streets."

Page 549

Do you see that?
A. Yes, I do.
Q. So, I mean, Endo is telling the FDA that it has reports as of at least May 22nd, 2008 of Opana ER being purchased on the street, correct?
MR. LIMBACHER: Object to form.
THE WITNESS: That apparently is what's in the report, yes.
BY MS. SCULLION:
Q. So Endo knew at that point, at least, if not earlier, that Opana ER had street value, correct?
MR. LIMBACHER: Object to form.
THE WITNESS: Well, it's acknowledging and reporting to the FDA that in this case that product was purchased on the street.
BY MS. SCULLION:
Q. Which meant it had street value, right?
MR. LIMBACHER: Object to form.
THE WITNESS: I'm not sure what street value means. It doesn't quantify

Page 550

it, but it was purchased, so I imagine there was an exchange of value of some sort.
BY MS. SCULLION:
Q. I mean, as your -- in your time with commercial responsibility for Opana ER, did you have any training on the concept of Opana ER or other opioid products being bought and sold on the street and having street value? Is that something you had training on?
MR. LIMBACHER: Object to form.
THE WITNESS: I don't understand what training would be with regards to street value.
BY MS. SCULLION:
Q. Were you given training on the ways in which narcotics like Opana ER could be diverted?
MR. LIMBACHER: Object to form.
THE WITNESS: That's a very different question.
BY MS. SCULLION:
Q. I'm asking a different question. Were you given training on that issue?

Page 551

A. All employees, as part of the code of conduct, especially those with involvement in our controlled substances had to undergo periodic training, certify their compliance with that, and within that context, generally, I would say that all employees were aware of the potential for diverse and abuse -- or abuse and diversion of the opioid product. So at that level, everyone was aware because it was part of the responsibility to watch out for that, and it's the underpinning of the RiskMAP and the REMS and all of the other documents.
Beyond that, I don't recall any specific training on street value or any of the like at that level, I don't.
Q. Putting your 30(b)(6) hat, your corporate representative hat back on, seeing all the reports of abuse, misuse, diversion of Opana ER over the years that were reported to the FDA in the RiskMAP updates, did Endo ever tell the FDA that its RiskMAP was ineffective to combat diversion or abuse?
MR. LIMBACHER: Object to the form and object as falling outside the

Page 552

scope of the topics on which he's been designated.
THE WITNESS: I don't know.
BY MS. SCULLION:
Q. Did -- in response to all the evidence of abuse and diversion of Opana ER over a number of years in which the RiskMAP updates were submitted to the FDA, did Endo ever change its policies or procedures with respect to combating diversion of Opana ER in response to that evidence?
MR. LIMBACHER: Same objections.
THE WITNESS: As we've testified before, the RiskMAP formed the basis in 2007 of a broad array of activities undertaken by the company. The RiskMAP report that you just focused me on from 2008, reports like that were done periodically as part of that. The RiskMAP was enhanced in 2012 with the industry-wide REMS, so I would say that constituted a change or an evolution of the policies and procedures.
There was a further evolution as

Page 553

a result of discussions with the New York Attorney General later, several years later.
So I would say that, yes, Endo's policies and procedures did evolve over time, but they were always grounded in the same principles that were put forward back in 2007 in the very comprehensive RiskMAP.
BY MS. SCULLION:
Q. So the question is, though, during the period when Endo had its RiskMAP in place, did Endo ever change its anti-diversion procedures in response to the growing evidence that Opana ER was being abused?
MR. LIMBACHER: Same objections, asked and answered.
THE WITNESS: Same answer. I mean, I can repeat the answer, if you would like.
BY MS. SCULLION:
Q. Well, the answer, as I understood, was that the change occurred, in your view, when REMS was implemented.

Before REMS, if I'm wrong, you'll tell me no, before REMS, did Endo change any of its anti-diversion procedures in response to the evidence of Opana ER abuse?

MR. LIMBACHER: Same objections, and I think you misstated his testimony.

BY MS. SCULLION:

Q. Please let me know if I did.

A. You did. So I'll explain again.

The principles as put forth in the 2007 REMS were the underpinning of all of the activities.

Q. Did you mean RiskMAP?

A. What did I say?

Q. REMS.

A. Strike that, please, or I'll repeat that. Thank you.

In the 2007 RiskMAP the principles that were put forward there were the -- formed the foundation of the broad array of activities that continue today. So the RiskMAP was not replaced by the REMS, it was supplanted by or it was supplemented by the REMS.

As I said, also, as a result of

discussions with the New York Attorney General several years later, there was some further evolutions of policies and procedures, but I can't attest that those are in response to any specific trigger or any specific event. They were in response to ongoing focus by a broad array of cross-functional experts within the company to make sure that the company was doing everything within its power to mitigate abuse and diversion. Again, those are the principles as put forward in the 2007 RiskMAP.

Q. Well, in response to the evidence of abuse of Opana ER, did Endo ever, for example, say, well, we want to go beyond just monitoring and we want to go out and actively look for pill mills and ensure that our product is not being supplied to pill mills?

MR. LIMBACHER: Same objections.

THE WITNESS: Endo certainly had safeguards in place to mitigate the chance that its products were being diverted to, as you say, pill mills. Whether that was in response to any one specific trigger, it was in response to

broad understanding that opioids had the potential of being abused and diverted.

BY MS. SCULLION:

Q. But can you identify any particular change Endo made to its anti-diversion procedures in response to growing evidence of Opana ER abuse, any specific, concrete changes that Endo made?

MR. LIMBACHER: Same objections.

THE WITNESS: As I said before, the REMS, industry-wide REMS was part of the evolution of the program. The changes put forward as a result of discussions with the New York Attorney General, the ADD program had several enhancements to it.

I would say that one of the changes Endo made in response to knowledge of the growing threat was to formulate a product that was designed to mitigate at least one of the forms of abuse of the product. So, yes, Endo undertook several steps to try and mitigate that problem.

BY MS. SCULLION:

Q. But the FDA didn't agree that, in fact, the reformulated version of Opana ER was any more effective at combating abuse, correct?

MR. LIMBACHER: Object to form.

BY MS. SCULLION:

Q. The FDA never accepted any data that Endo put forward on that point?

MR. LIMBACHER: Object to form.

THE WITNESS: Oh, FDA accepted all the date we submitted.

BY MS. SCULLION:

Q. It didn't accept the conclusion that reformulated Opana ER was, in fact, abuse deterrent, right; they never made that finding?

MR. LIMBACHER: Object to form.

THE WITNESS: Correct. At the end of the submission and the evaluation, the FDA ultimately did not agree, but they accepted everything we submitted.

BY MS. SCULLION:

Q. Now, you just referenced REMS --

A. Yes.

Page 662

clearly that the DEA, first of all, by the fact that they allowed us to have this meeting with the fairly high ranking number of DEA personnel was quite remarkable, and I recall them indicating to us that they were also -- they shared our objective of making incremental steps to try and mitigate abuse of in this case -- in our case of Opana. They recognized that crushing and snorting was an important route of abuse and misuse, and they were particularly aligned with our efforts in support of -- in fact, there's some text in here that indicates the DEA being highly aligned with Endo's plan to introduce a new formulation as quickly as possible.

And, again, generally, I recall them recognizing and being in alignment with our recognition of the problem and our plans to try to address it.

MS. SCULLION: Note also my objection to the hearsay.

Page 663

BY MR. LIMBACHER:

Q. If you have in front of you Exhibit 55. I wanted to ask you a couple of questions about that. That's one of the exhibits that counsel from Tennessee was asking you about.

A. And you said 55?

Q. Yes.

A. Thank you. Sorry about that.

Q. Take a look at Exhibit 55.

Do you recall being asked questions about this particular document by counsel representing plaintiffs from Tennessee?

A. Yes, I do.

Q. And do you recall that the questions you were being asked suggested that Endo considered abuse and misuse an issue of mere perception?

A. I do recall that, yes.

Q. Did he show you various pages from the slide deck that is attached to the first page of Exhibit 55?

A. Yes, he did.

Q. Let me refer you to slide number

Page 664

6 of Exhibit 55. It has the heading "Abuse & Misuse Overview."

A. Yes, I have slide 6.

Q. Did counsel show this particular slide to you?

A. I do not believe he did, no.

Q. Can you summarize for us what's set forth on this particular slide?

MS. SCULLION: Objection to form, foundation. As I recall, the objection was made to the witness testifying about the slide deck on the grounds that he did not recall it.

BY MR. LIMBACHER:

Q. You can go ahead and answer the question.

A. Thank you. So what I read on this slide is that it's acknowledging -- that the author is acknowledging after the previous slides to set up whatever the discussion is and, again, just to reinforce, I wasn't part of that discussion, so I don't know who the audience was or the context, but after setting that up with some of the previous slides that I reviewed, the

Page 665

author now states that abuse and misuse, at least in the view of the author, is a real public health epidemic, a real public health epidemic and has several points of support for that statement, including number of overdoses, deaths related to overdoses, how many Americans reported nonmedical use of prescription pain medications, emergency department visits, nonmedical use of prescriptions medications costing health insurers billions of dollars.

So it puts into context, I think, a view on the seriousness of the abuse and misuse of controlled substances.

Q. We've been here two days and you've answered a lot of questions, Mr. Lortie. I just want to have you step back for just a moment and ask you how would you describe Endo's efforts to minimize the risk of abuse and diversion of Opana?

MS. SCULLION: Objection to form.

THE WITNESS: I spent seven years or so there in a senior position, always with some close proximity to the pain business, and it was a company that was

Page 666

deeply rooted in pain therapeutics and, therefore, believed importantly that patients who suffer from chronic pain deserve access to medicines that help them live as nearly normal a life as possible.

The company always also recognized that there's a potential for diversion and misuse and abuse of these medicines. That's been long established long before I got there.

And, therefore, always had in place not just policies and procedures and professionals whose job it was to play an important role in making sure to the extent of the company's capabilities that that was taken seriously and necessary steps were taken, but also a company culture of compliance with regulations and the spirit so that there wasn't jeopardy to patients who deserved to have access to important medicines to live their normal lives.

So it was not just company

Page 667

activity, but it was really a cultural aspect of compliance, and I'm proud of my time there. I really feel that the company did what it could and always took it very seriously.

MS. SCULLION: Move to strike as improper narrative.

MR. LIMBACHER: Thank you, Mr. Lortie. That's all the questions I have.

THE VIDEOGRAPHER: Going off the record at 7:43 p.m.

(Brief recess.)

THE VIDEOGRAPHER: We are back on the record at 8:01.

BY MS. SCULLION:

Q. Mr. Lortie, welcome back.

Counsel had asked you to describe Endo's efforts to minimize their risk of abuse and diversion of Opana.

Do you remember he asked that question?

A. Yes, I do.

Q. Okay. Now, the fact is that Endo

Page 668

withdrew original Opana ER for safety reasons, correct, discontinued for safety reasons?

MR. LIMBACHER: Object to form.

THE WITNESS: That was our understanding at the time, yes.

BY MS. SCULLION:

Q. And the safety reasons for which Endo cited for the withdrawal were that Opana ER was subject to both intentional and inadvertent abuse and misuse, correct?

MR. LIMBACHER: Object to form.

THE WITNESS: I believe that to be the case at the time. That was the company's understanding, yes.

BY MS. SCULLION:

Q. And, in fact, throughout the time that Endo was submitting RiskMAP updates to the FDA, Endo was consistently noting case after case of abuse and misuse of Opana ER, correct?

MR. LIMBACHER: Object to form.

THE WITNESS: The subject of the RiskMAP -- of the RiskMAP updates would have included that type of information, that is correct.

Page 669

BY MS. SCULLION:

Q. Let's look at some of the RiskMAP updates. Can you pull back Exhibit Number 50.

A. I will find it, yes.

Q. Do you have Exhibit Number 50 in front of you?

A. I do have Exhibit Number 50, yes.

Q. Okay. And this is the RiskMAP update report we looked at before dated May 22nd, 2008.

Can you turn to page 20 of that exhibit?

A. Sure.

Q. You see under "Periodic Reports" that Endo reports to the FDA that there were a total of 306 adverse event reports submitted to the agency since approval of the product, correct?

A. Yes, that's correct.

Q. Endo then goes on to state in the last sentence of that paragraph, "Post marketing safety surveillance of Opana ER since launch has not identified any new safety issues," correct?

A. That's what it says, yes.

Page 670

Q. Right. And then that was the update report covering January 1st, 2008 to March 31st, 2008.

Let's look at the next year.

(Document marked for identification as Endo-Lortie Deposition Exhibit No. 61.)

BY MS. SCULLION:

Q. Show you what's been marked as Exhibit 61.

And Exhibit 61 for the record is Bates stamped EPI000119179, and this is a RiskMAP Update Report covering the period January 1st, 2009 to March 31st, 2009.

If you could turn to page 16 of this RiskMAP Update Report. And again looking under "Post Marketing Surveillance," 6.1, do you see the last sentence of that paragraph, Endo once again reports "Post marketing surveillance of Opana ER since launch has not identified any new safety issues."

Did I read that correctly?

A. Let me just catch up to you here. And that's in paragraph 6.1, correct.

Page 671

Q. Last sentence.

A. Periodic reports.

Yes, I believe you read that accurately.

Q. And let's look now at the report for January 1st, 2010 to March 31st, 2010.

(Document marked for identification as Endo-Lortie Deposition Exhibit No. 62.)

BY MS. SCULLION:

Q. It's Exhibit Number 62.

And it's Bates stamped ENDO-OR-CID-00681354. And here again, if you'll turn to page 15 of this RiskMAP update, bottom of the page, "Post Marketing Surveillance, Periodic Reports," and the paragraph carries over to the top of the next page, page 16, and, once again, at the end of that paragraph, Endo reports "Postmarketing surveillance of Opana ER since launch has not identified any new safety issues," correct?

A. Yeah, I read that as any new safety issues, in other words, any new safety issues that have not been previously described

Page 672

in terms of the definition of them.

Q. It's the same sentence in every report so far, right?

MR. LIMBACHER: Object to form.

THE WITNESS: I'm not sure.

(Document marked for identification as Endo-Lortie Deposition Exhibit No. 63.)

BY MS. SCULLION:

Q. So then let's go to the report for the period January 1st, 2011 to March 31st, 2011. I hand you what's been marked as Exhibit Number 63.

And that is Bates stamped END00308793.

And, again, if you'll turn to page 18, section "Post marketing Surveillance," subsection 6.1, "Periodic Reports."

A. Can you just let me catch up to where you are.

Q. Sure.

A. Okay, thank you. You said 18, correct?

Q. Correct. Do you see paragraph

Page 673

6.1 Periodic Reports?

A. I do.

Q. And, again, Endo reports to the FDA "Postmarketing surveillance of Opana ER since launch has not identified any new safety issues."

That's what it says, right?

A. You read that correctly.

Q. Okay. And let's look at the report for the last half of 2011.

(Document marked for identification as Endo-Lortie Deposition Exhibit No. 64.)

BY MS. SCULLION:

Q. Hand you what's been marked as Exhibit Number 64.

And Exhibit 64 is Bates stamped EPI000015268.

And if you'll turn in this exhibit to page 18, I direct your attention again to the section "Post Marketing Surveillance," paragraph 6.1, "Periodic Reports."

Are you with me?

Page 674

A. Yes, on the top of 18.
Q. And, once again, for the period July 1st, 2011 to September 30th, 2011, Endo's reporting "Postmarketing surveillance of Opana ER since launch has not identified any new safety issues."
Did I read that correctly?
A. Yes, you did.
Q. Now, as we saw earlier in your testimony, as of May 2011, the DEA for the Philadelphia area office had, in fact, identified that there was evidence of widespread abuse of Opana ER, correct?
MR. LIMBACHER: Object to form, foundation.
THE WITNESS: I'd be happy to look at that document again. We saw it a while ago.
BY MS. SCULLION:
Q. It's in the record.
So now let's turn to the RiskMAP Update Report for the period October 1st, 2011 to December 31st, 2011, and I'll note it's dated March 7th, 2012.

Page 675

(Document marked for identification as Endo-Lortie Deposition Exhibit No. 65.)
BY MS. SCULLION:
Q. It's Exhibit 65.
And Exhibit 65 is Bates stamped ENDO-OR-CID-01044118.
A. Yes, I have that.
Q. Okay. Now, if you'll go to page 4 of this report, under the heading "Introduction," looking at the second paragraph, and Endo reports to the FDA, "Overall, during this period no safety signals have been identified and no patterns have diversion were observed in the supply chain."
Did I read that correctly?
MR. LIMBACHER: Object to form.
THE WITNESS: That's -- you read the sentence accurately.
BY MS. SCULLION:
Q. Next sentence, "Based on the available data, no new trends were observed, but abuse and misuse of Opana and Opana ER continues to be a problem."

Page 676

Do you see that?
A. Yes, again, you read that correctly.
Q. Okay. So Endo is acknowledging finally in this report that abuse and misuse of Opana ER is a problem, nonetheless Endo is saying there's no safety signal; is that correct?
MR. LIMBACHER: Object to form, misstates the evidence.
THE WITNESS: Well, you pointed me to a different spot. I'd be happy to go back and look at the other exhibits. We didn't look at the introduction, so I can't comment on the -- whether or not the comment about abuse and misuse of Opana and Opana ER continues to be a problem. I suspect it's in the introduction of the other documents as well.
BY MS. SCULLION:
Q. Well, if you look at the date for Exhibit 65, this is dated March 7th, 2012, correct?

Page 677

A. That's the date of the report, yes.
Q. And as of that date, Endo now had FDA approval for its reformulated version of Opana ER, correct?
A. Well, as of March 7th it did. Of course, the period is covering December 31st, the product had just received approval, but it was not yet marketed. In fact, in March of 2012 it was not on the market.
Q. But as of the date of the report, Endo had in hand now approval to launch a new product, correct?
A. FDA approval was received in December of 2011, but there was some time to ensure manufacturing of adequate supply before it was put into the marketplace.
Q. And the question is, though, as of the date of this report, Endo now had in hand FDA approval for a reformulated version of Opana ER, right?
A. As of the time of the report it did, yes.
Q. And Endo's intention was to

Page 678

substitute the reformulated version of Opana ER for the original version, correct?
MR. LIMBACHER: Object to form and foundation.
THE WITNESS: The plan was to effect as smooth as possible a transition between the original formulation and new formulation, the key objective being to ensure that patients who were titrated to effect were not -- didn't experience an interruption in supply. We had some challenges doing that but...
BY MS. SCULLION:
Q. But Endo intended at the end of that to have the newly reformulated version of Opana ER replace the old version, correct?
MR. LIMBACHER: Same objections.
THE WITNESS: The ultimate plan was to have only the new version on the market.
BY MS. SCULLION:
Q. Correct.
And, as we discussed before,

Page 679

Endo's intent was to have that reformulated version approved as an abuse deterrent formulation, correct?
MR. LIMBACHER: Same objections.
THE WITNESS: That was the intent and the objective, yes.
BY MS. SCULLION:
Q. Right, and the FDA never approved the reformulated product as an abuse deterrent formulation, correct?
MR. LIMBACHER: Object to form, asked and answered.
THE WITNESS: Ultimately, after much deliberation and submission of data and negotiations and discussions, that's correct, they have not yet or they never did finally approve that language.
BY MS. SCULLION:
Q. And you're aware, are you not, that after a number of years of selling the reformulated product, Endo withdrew that product after the FDA had determined that the abuse of the reformulated product also showed that its risks outweighed its benefits from a safety

Page 680

perspective, correct?
MR. LIMBACHER: Object to form and outside the scope of the direct.
THE WITNESS: I understand that is what eventually happened. That, of course, happened after I left the company, so I wasn't part of that decision.
BY MS. SCULLION:
Q. So, overall, the original Opana ER proved to be too unsafe because of abuse, and the reformulated version of Opana ER likewise proved to be too unsafe because of abuse, correct?
MR. LIMBACHER: Objection, form foundation and misstates the evidence.
THE WITNESS: Yeah, I don't think I can agree with that, so I disagree.
MS. SCULLION: I have no further questions.
THE VIDEOGRAPHER: That concludes today's deposition. The time is 8:14 p.m.
(Brief recess.)

Page 681

(Deposition resumes at 8:15 p.m.)
MR. LIMBACHER: We have no questions.
(Witness excused.)
- - -

C E R T I F I C A T I O N

I, MARGARET M. REIHL, a Registered Professional Reporter, Certified Realtime Reporter, Certified Shorthand Reporter, Certified LiveNote Reporter and Notary Public, do hereby certify that the foregoing is a true and accurate transcript of the testimony as taken stenographically by and before me at the time, place, and on the date hereinbefore set forth.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in the action.

Margaret M. Reihl, RPR, CRR, CLR
CSR #XI01497 Notary Public

- - - - - -

E R R A T A

- - - - - -

PAGE LINE CHANGE

____ ____ _____

REASON: _____

____ ____ _____

REASON: _____

____ ____ _____

REASON: _____

____ ____ _____

REASON: _____

____ ____ _____

REASON: _____

____ ____ _____

REASON: _____

____ ____ _____

REASON: _____

____ ____ _____

REASON: _____

____ ____ _____

REASON: _____

____ ____ _____

REASON: _____

____ ____ _____

REASON: _____

____ ____ _____

REASON: _____

ACKNOWLEDGMENT OF DEPONENT

I, BRIAN LORTIE, do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____

BRIAN LORTIE DATE

Subscribed and sworn to before me this

_____ day of _____, 2018.

My commission expires:_____

_____

Notary Public